

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF PUERTO RICO**

LILLIAM IRIZARRY-CASIANO.

## **Plaintiff,**

V.

Civil No. 13-1051 (GAG)

**NOVARTIS PHARMACEUTICALS  
CORPORATION, et al.,**

## **Defendants.**

## **MEMORANDUM OPINION**

Plaintiff alleges she was stricken with glaucoma and carpal tunnel from using Defendant's product, Reclast, and that Defendant "did not warn that Reclast was not for people [such as Plaintiff] suffering from" calcium deficiency. (Docket No. 16 at 4.) To succeed in a products liability suit in Puerto Rico, a plaintiff must demonstrate that "there were no warnings or instructions, or those provided were inadequate," and that the "absence of adequate warnings or instructions was the proximate cause of plaintiff's injury." Cruz-Vargas v. R.J. Reynolds Tobacco Co., 348 F.3d 271, 276 (1st Cir. 2003).

Plaintiff alleges, “Had [D]efendant properly labeled the product, the same would have not been prescribed to [Plaintiff] and she would have not” suffered glaucoma or carpal tunnel. (Docket No. 16 at 4.) The FDA, to wit, warns against its use by those with low calcium and that it can cause bone, joint, or muscle pain. (See Docket No. 13.) Plaintiff, furthermore, cites websites whose credibility the court cannot weigh at this stage. (Id.) Plaintiff satisfies her burden of pleading that the label or package insert insufficiently warned users of the FDA’s admonishments. Because the motion to dismiss and sur-reply fail to discuss the specifics of the warning’s adequacy on the label

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or in the drug's package insert, this issue requires resolution of factual issues beyond the court's current grasp.

This issue may not require extensive discovery. “A prescription drug manufacturer has a duty to adequately warn prescribing physicians of the hazards posed by the use of its drugs.” Guevara, 845 F.2d at 366. Furthermore, “The warning is directed not to the ultimate user but to the doctor prescribing the drug, who must then ‘take into account the propensities of the drug and the susceptibilities of the patient and make an informed decision.’” Id. (citation omitted). The First Circuit has determined that, as a matter of law, when the Physician’s Desk Reference and package insert that comes with a drug warn physicians not to give the drug to persons with certain sensitivities, then a warning is adequate. See id. Resolving this issue turns on the contents of the warning, which the court does not presently have. For now, Plaintiff’s statement that Defendant failed to properly warn the label to tip off a doctor that a calcium-deficient might suffer potential dangers of Reclast’s side-effects. Therefore, Defendant’s motion to dismiss at Docket No. 17 is **DENIED.**

16 || SO ORDERED

In San Juan, Puerto Rico this 27th day of June, 2013.

/S/ Gustavo A. Gelpí  
**GUSTAVO A. GELPI**  
United States District Judge